

CLAIMS

1. A sustained-release formulation comprising:
 - (a) a sustained-release core comprising an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions;
 - (b) an enteric film coating layer coated on the sustained-release core; and
 - (c) an active ingredient-containing film coating layer coated on the enteric film coating layer and comprising the active ingredient and a hydrophilic polymer for film coating.
2. The sustained-release formulation of claim 1, which further comprises an outer coating layer coated on the active ingredient-containing film coating layer and comprising a film coating polymer selected from the group consisting of a hydrophilic polymer, a hydrophobic polymer, a pH-dependent polymer, and a combination thereof.
3. The sustained-release formulation of claim 1 or 2, wherein the polymer contained in the sustained-release core is a polymer having a viscosity of 1 to 100,000 mPa.s.
4. The sustained-release formulation of claim 1 or 2, wherein the hydrophilic polymer contained in the active ingredient-containing film coating layer is a hydrophilic polymer having a viscosity of 1 to 100,000 mPa.s.
5. The sustained-release formulation of claim 1 or 2, wherein the polymer contained in the sustained-release core is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hydroxymethylcellulose, polyethylene oxide, waxes (Carnauba wax), sodium alginate, povidone, polyvinylalcohol, sodium carboxymethylcellulose, xanthan gum, alginic acid salt and its derivative, and a combination thereof.
6. The sustained-release formulation of claim 5, wherein the polymer contained in the sustained-release core is hydroxypropylmethylcellulose.
7. The sustained-release formulation of claim 1 or 2, wherein the content of

the polymer in the sustained-release core is 1 to 99 wt%, based on the total weight of the sustained-release core.

8. The sustained-release formulation of claim 1, wherein the enteric film coating layer includes an enteric polymer which is soluble at about pH 5 or more.

9. The sustained-release formulation of claim 2, wherein the polymer contained in the outer coating layer is an enteric polymer which is soluble at about pH 5 or more.

10. The sustained-release formulation of claim 8 or 9, wherein the enteric polymer is selected from the group consisting of cellulosic polymers, polyvinyl polymers, maleic acid vinyl polymers, polymethacrylate copolymers, and combinations thereof.

11. The sustained-release formulation of claim 8 or 9, wherein the enteric copolymer is a 1:1 copolymer of methacrylic acid and ethylacrylate.

12. The sustained-release formulation of claim 1 or 2, wherein the hydrophilic polymer contained in the active ingredient-containing film coating layer is selected from the group consisting of polyvinylalcohol, polyethyleneglycol, polypropyleneglycol, acrylic acid copolymer, hydroxypropylmethylcellulose, hydroxypropylcellulose, methylcellulose, ethylcellulose, and a combination thereof.

13. The sustained-release formulation of claim 1 or 2, wherein the active ingredient is a drug selected from the group consisting of antihypertensive agents, antidiabetes agents, antilipemic agents, cardiovascular drugs, expectorants, antibiotics, emollients, steroids, antiasthmatic drugs, nonsteroid anti-inflammatory agents, therapeutic agents for prostatic enlargement, antidepressants, antihistamines, and combinations thereof.

14. The sustained-release formulation of claim 13, wherein the active ingredient is nifedipine, felodipine, cetirizine, pseudoephedrine, tamsulosin, or a pharmaceutically acceptable salt thereof.

15. The sustained-release formulation of claim 14, wherein the active ingredient is tamsulosin or its hydrochloride.

16. The sustained-release formulation of claim 15, wherein 60 to 99 wt% of tamsulosin is contained in the sustained-release core and 1 to 40 wt% of tamsulosin is contained in the active ingredient-containing film coating layer.